Statistical Plan, Results and Conclusions for:

A Clinical Decision Support Tool for Electronic Health Records (Official Title)

NCT number 02697643

Document Date: August 9, 2018
Analytic Approach.

**Primary Analytic Approach.** We are interested in learning whether participants in the intervention condition, BH-CDS, as compared to the control condition, treatment as usual, have (1) greater access to wraparound services, (2) more treatment visits, and (3) longer retention in treatment. As secondary hypotheses, we will examine whether the intervention condition, as compared to the control condition, will be associated with significantly (1) greater psychosocial outcomes, and (2) reduced drug use. A mixed model analytic approach was chosen for its ability to: adjust for individual-level covariates; take into account nesting of clients within counselors; and efficiently maximize the correlated nature of the repeated measures data in the design. Each mixed model will include fixed effects (condition, time and condition-by-time); random effects (clients nested within counselors); repeated measures variation (time); as well as potential counselor-level demographic covariates (e.g., experience level) and client-level demographic covariates (i.e., age). Non-significant covariates will be removed systematically. After arriving at the final model for each analysis, the condition-by-time effect will be examined for significance. In the presence of a significant condition-by-time effect, Bonferroni corrected post-hoc contrasts will be conducted to test for differences between conditions on mean change from baseline to one month follow-up and baseline to three month follow-up.

**Analyses by Hypothesis**

*Primary Hypothesis 1: Clients in the experimental condition will have significantly greater matched evidenced-based and wraparound services than clients in the control condition.* To address this hypothesis, a chart review was conducted to enumerate services received during the study period. The percentage of services that clients in the experimental condition received from the list of tailored recommendations was calculated. We then compared this percentage to the percentage of services that clients in the control condition would have received had they been in the experimental condition and received tailored recommendations. Because all clients participating in the study completed the PDE, we were able to determine which set of recommendations clients in the control condition would have received had they been in the experimental.

*Primary Hypothesis 2: Clients in the experimental condition will have greater engagement in treatment than clients in the control condition.* Engagement in treatment was calculated by dividing the number of treatment sessions attended during the study period by the total number of scheduled treatment sessions (i.e., opportunities for treatment), a sum of treatment sessions attended plus the number of scheduled sessions that the client did not show up for (no-show). An independent samples T-test was utilized to determine whether there were statistically significant differences between participants in the experimental and control groups with respect to treatment engagement.

*Primary Hypothesis 3: Clients in the experimental condition will have less frequent use of substances than clients in the control condition.* Use of substances was measured by the number of relapses during the study period. An independent samples T-test was conducted to evaluate whether participants number of relapses differed significantly between the experimental and control groups.

*Primary Hypothesis 4: Clients in the experimental condition will have greater biopsychosocial functioning than clients in the control condition.* Biopsychosocial functioning was captured by the seven ASI-MV composite scores. The ASI-MV was administered at baseline, 1-month follow-up and 3-month follow-up. Change in the ASI-MV composite scores was evaluated over time and across participant groups with a repeated measures mixed model.

*Primary Hypothesis 5: Clients in the experimental condition will have greater cost effectiveness than clients in the control condition.* Costs of services provided to the participating clients in the experimental and control conditions during the study time period was estimated in the following way. Services received by each client as documented during the chart review process for Hypothesis 1 above. The
cost of each service was estimated using the CPT code for that service (e.g., group psychotherapy = 90853). To establish consistent costs, estimates of cost for each CPT code were derived from Medicare reimbursement estimates in Massachusetts using online tools (e.g., https://www.findacode.com). While not precise, use of Medicare reimbursement is often used to get a general and relative sense of service costs across states. This is especially useful for comparing groups (e.g., experimental versus control), rather than attempting to generate precise cost estimates. Costs per individual were summed and averaged for t-test comparison between experimental and control groups. If patient outcomes are superior for one group, this test would determine whether the outcome difference is associated with greater or lesser costs.

**Primary Hypothesis 6: Counselors in the experimental condition will report satisfaction with the BH-CDS Program.** At the end of the study, participating counselors were asked to complete a satisfaction survey, which included both open-ended questions and Likert-type rating scale questions. Due to the small number of counselors in the experimental and control groups, formal statistical significance testing was not conducted. Instead, these data were analyzed descriptively. Open-ended text were subject to qualitative thematic analysis.

**Results**

**Counselor Participants.** A total of 24 counselors at four outpatient substance abuse treatment facilities around the United States participated in the current study.

**Client Participants.** One hundred and ninety patients completed consent forms and completed baseline surveys. Of these, 140 participants were fully enrolled into the study (completed the PDE, counselors obtained recommendations from the BHCDS system, participants completed the baseline survey). Forty-seven participants were randomized into the control, TAU, condition and 93 were randomized into the experimental condition. Demographics were relatively similar across the experimental and control conditions.

**Primary Hypothesis 1:** Clients in the experimental condition will have significantly greater matched evidenced-based and wraparound services than clients in the control condition. Results test indicated no significant difference for experimental and control groups.

**Primary Hypothesis 2:** Clients in the experimental condition will have greater engagement in treatment than clients in the control condition. T-tests indicated that the experimental and control groups did not differ with respect to treatment engagement.

**Primary Hypothesis 3:** Clients in the experimental condition will have less frequent use of substances than clients in the control condition. The mean number of relapses during the study period for the experimental group was not significantly different from the control group.

**Primary Hypothesis 4:** Clients in the experimental condition will have greater biopsychosocial functioning than clients in the control condition. Results for psychiatric status, medical status, alcohol use, family status, or drug use were not significant. Employment status results suggest that participants in the experimental, CDS, condition had significantly fewer legal problems than controls.

**Primary Hypothesis 5:** Clients in the experimental condition will have greater cost effectiveness than clients in the control condition. The CDS program did not yield significantly different costs effectiveness than the control group.
Primary Hypothesis 6: Counselors in the experimental condition will report satisfaction with the BH-CDS Program. Overall, counselors found it easy to complete the CDS program and reported that their clients' reaction was "neutral" or "positive" (no counselors reported a negative client reaction).

Counselors exposed to the tailored recommendations, reported that they were easy to understand, easy to integrate into the client's treatment plan, and useful for informing treatment decisions and were more likely to incorporate the tailored recommendations into future treatment planning.

Conclusion
Although the use of clinical decision support is promising, the present effort was unable to empirically demonstrate a direct impact on outcome, retention, amount of service delivered or cost. Further research on the impact of clinical decision support for substance use treatment is warranted.